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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/773,628	02/05/2004	Matti Sallberg	TRIEP.056A	8484

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EXAMINER

HUMPHREY, LOUISE WANG ZHIYING

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 10/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary**Application No.**

10/773,628

Applicant(s)

SALLBERG, MATTI

Examiner

Louise Humphrey, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-45 is/are pending in the application.
- 4a) Of the above claim(s) 32-34 and 36-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26-31 and 35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 5/28/04, 11/24/04, 2/28/05.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

The Office acknowledges the receipt of Applicant's election and Amendment, filed on 29 September 2006. Claims 1-25 have been cancelled. Claims 26-45 have been newly added. However, only claims 26-37 read on the elected product invention.

Election/Restriction

Applicant elects the species of ligand/receptor, virus target, CD4 peptide component, and SEQ ID NO:7. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 26-45 are pending. Claims 32-34, 36, 37, and 38-45 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species and invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 29 September 2006.

Claims 26-31 and 35 are currently examined.

Information Disclosure Statement

Initialed and dated copies of Applicant's IDS forms 1449, filed on 28 May 2004, 24 November 2004, and 28 February 2005, respectively, are attached to the instant Office action.

Double patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 26-31 and 35 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 3, 8-11, 17, and 24 of copending Application No. 10/913,754. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are anticipated by the copending claims. Both sets of claims are drawn to the same product with exactly the same ingredients.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 26-31 and 35 are rejected under 35 U.S.C. §103(a) as being unpatentable over Wang (WO 99/66957) in view of Galili *et al.* (1996).

The instant claims are drawn to an isolated glycosylated peptide comprising a binding fragment of a CD4 receptor for HIV gp120 joined to Gal $\alpha(1,3)$ Gal β .

Wang describes artificial T helper cell epitope and derived immunogens with target antigenic site, for immunization against malaria, arteriosclerosis or human immune deficiency virus. Particularly, an artificial Th epitope/target antigenic site peptide immunogen was designed with a sequence modified from the CDR2-like domain of CD4 (SEQ ID NO:88), which comprises the amino acid sequence of the instantly claimed SEQ ID NO:7. See page 38. Wang does not describe joining the fragment of CD4 receptor to Gal $\alpha(1,3)$ Gal β .

Galili *et al.* describe influenza virus hemagglutinin with the carbohydrate epitope Gal α 1-3Gal β 1-4GlcNAc-R (termed the α -gal epitope). Galili *et al.* specifically suggest that the immunogenicity of inactivated viruses or subviral vaccines may be enhanced by forming a complex with an IgG antibody. The natural anti-Gal antibody is ubiquitously produced as 1% of circulating IgG in humans and it interacts specifically with the α -gal epitope. Such antibody would increase the uptake, processing and presentation of the

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vaccine's antigens by antigen presenting cells (APC), via the adhesion of the antibody-vaccine complex to Fc-receptors on macrophages and other APC. See Abstract.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the fragment of CD4 receptor of Wang by glycosylation with an α -gal epitope, as suggested by Galili *et al.* The skilled artisan would have been motivated to do so to enhance presentation by APC of the CD4-ligand to specific helper T cell clones. There would have been a reasonable expectation of success, given that the natural form of a CD4 receptor contains oligosaccharides at two asparagines residues and the various approaches for achieving α -gal epitope expression on virion and subviral vaccines as discussed by Galili *et al.*

Remarks

No claim is allowable.

Applicant is reminded that any amendment must point to a basis in the specification so as not to add new matter. See MPEP §714.02 and §2163.06.


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Contact Information


Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise Humphrey, Ph.D. whose telephone number is 571-272-5543. The examiner can normally be reached on Mon-Fri, 9:30 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Jeffrey Parkin, Ph.D.
Primary Examiner
12 October 2006



10/12/2006